K010988

JUN 1 9 2001

510(K) Summary

Disc-O-Tech Medical Technologies Ltd.
Fixion Interlocking Proximal Femoral Nailing System

Company Name

Disc-O-Tech Medical Technologies, Ltd.
3 Hasadnaot St., Herzelia
Israel, 46728

Submitter's Name and Contact Person

Jonathan S. Kahan, Esq.
555 Thirteenth Street, NW
Washington, DC 20004
Tel: 202-637-5794
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Date Prepared

March, 2001

Trade/Proprietary Name

Fixion™ Interlocking Proximal Femoral Nailing System

Classification Name

Intramedullary Fixation Rod
21 C.F.R. § 888.3020
Class II

Predicate Devices

1. Fixion Interlocking Nailing System (K002783) by Disc-O-Tech.
2. Proximal Femoral Nail (K970097) by Synthes.

Performance Standards

The following standards were used:

1. The Interlocking Nail is manufactured from 316L Stainless Steel, which meets the requirements of ASTM F138 - Standard Specification for Stainless steel Bar and Wire for Surgical Implants.
2. The 4 point bending mechanical testing was performed according to ASTM F1264 - Standard for Mechanical Performance Considerations for Intramedullary Fixation Devices.
3. The Hip Peg testing was performed according to ASTM F384-99 – Standard Specification for Metallic Angled Orthopedic Fracture Fixation Devices.

Intended Use

The *Fixion Interlocking Proximal Femoral Nailing System* ("Fixion PF") is intended for use in fixation of fractures in the femur. It is indicated for use in fractures in the femur

shaft and proximal femoral fractures and combinations of these fractures. Proximal femoral fractures include stable and unstable pertrochanteric, intertrochanteric and subtrochanteric (with and without break-off of the minor trochanter), high subtrochanteric fractures and combinations of these fractures. Shaft fractures include those that are 5cm below the surgical neck to 5cm proximal to the distal end of the medullar canal.

The Fixion PF is also indicated for use in osteotomy, nonunions and malunions, bone reconstruction following tumor resection, grafting and pathological fractures, and revision procedures.

System Description

The Fixion Interlocking Proximal Femoral Nailing System is a single use system that consists of the following components:

1. The **Nail implant** is an expandable non-slotted stainless steel cylindrical tube, with a cap protected, female threaded proximal end with holes for Femoral Neck Peg and Hip Pin, to fix fractures in the proximal femur.
2. The **Inflation device** is a single-use manual plastic pump that is filled with sterile inflation liquid an used to inflate the nail implant and Femoral Neck Peg.

Once the nail and the Femoral Neck Peg and hip pin are positioned within the medullary canal and femur neck, rotation of the "pump" handle allows for screw and nail diameter increase to their intended diameter under X-ray and controlled pressure.

Substantial Equivalence

The Fixion Interlocking Proximal Femoral Nailing System Nail has substantially equivalent intended use and indications as the Fixion™ Interlocking Nail and the Synthes Proximal Femoral Nail, i.e., fixation of fractures of the femur.

The performance characteristics of the Fixion Proximl Femoral Nail have been tested and found to meet the specifications through a series of bench tests.

The Fixion Interlocking Proximal Femoral Nail, like the Fixion™ Interlocking Nail, is made of 316L Stainless Steel and has cannulated design. The cross section of the Fixion Interlocking Proximal Femoral and the Fixion Interlocking nails is circular with reinforcement bars.

Fixation of the Fixion Interlocking Proximal Femoral and Interlocking nails is achieved by inflation and results in the attachment of the 4 reinforcement bars to the medullary canal wall. The addition of Femoral Neck Peg and Hip Pin provides equivalent fixation to the end of the nail, in a manner that is substantially equivalent to that of the Synthes Proximal Femoral Nail. The inflation of the Fixion Interlocking Proximal Femoral nail with saline, which is a non-compressible biocompatible fluid, is identical to the cleared Fixion Interlocking nail and does not raise any new safety and efficacy issues.

Premarket Notification Truthful and Accurate Statement*
(As required by 21 CFR 807.87(j))

I certify that, in my capacity as the General Manager of Disc-O-Tech Medical Technologies, Ltd., I believe to the best of my knowledge, that all data and information submitted in the premarket notification for the Fixion Interlocking Nailing System are truthful and accurate and that no material fact has been omitted.

E.K
Signature

Elad Magal – General Manager
Typed Name and Title

Disc-O-Tech Medical Technologies, Ltd.
Company

03 / 28 / 01
Date

Premarket Notification 510(k) Number

* Must be signed by a responsible person of the firm required to submit the premarket notification (e.g., not a consultant for the 510(k) submitter)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 9 2001

Disc-O-Tech Medical Technologies, LTD.
c/o Mr. Johnathan S. Kahan, Esq.
555 Thirteenth Street, NW
Washington, DC 20004

Re: K010988
Trade Name: Fixion Interlocking Proximal Femoral Nailing System
Regulation Number: 888.3020
Regulatory Class: II
Product Codes: HSB
Dated: March 28, 2001
Received: April 2, 2001

Dear Mr. Kahan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(K) Number (if known): K010988

Device Name: Fixion Interlocking Proximal Femoral Nailing System

Indication for Use:

The *Fixion Interlocking Proximal Femoral Nailing System* ("Fixion PF") is intended for use in fixation of fractures in the femur. The Fixion PF is indicated for use in fractures in the femur shaft, proximal femoral fractures, and combinations of these fractures. Proximal femoral fractures include stable and unstable pertrochanteric, intertrochanteric and subtrochanteric (with and without break-off of the minor trochanter), high subtrochanteric fractures and combinations of these fractures. The long Fixion PF may also be used in mid shaft fractures, 5cm below the surgical neck to 5cm proximal to the distal end of the medullar canal.

The Fixion PF is also indicated for use in osteotomy, nonunions and malunions, bone reconstruction following tumor resection, grafting and pathological fractures, revision procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(per 21 CFR 801.109)

OR Counter Use _____

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010988